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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,531	06/24/2005	Toshiyuki Kanamori	040894-7268	3550

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MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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07/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/540,531

Applicant(s)

KANAMORI ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-10 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/24/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

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Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Cited in IDS filed 24 June 2005).

Instant claim 1 is drawn to a cell separation and recovery apparatus, which comprises: a treatment part having a non-woven fabric which is bound with a polymer showing a hydrophobic nature at a temperature higher than a predetermined temperature and showing a hydrophilic nature at a temperature lower than the predetermined temperature and a physiologically active substance capable of binding to target cells, and a liquid temperature controlling part for controlling liquid temperature of the treatment part, wherein the cells captured on the non-woven fabric are released and recovered from the non-woven fabric by changing the liquid temperature of the treatment part around the prescribed temperature with the liquid temperature controlling part. Claim 2 specifies that the physiologically active substance is bound to the non-woven fabric via the polymer. Claim 6 specifies that the capture of cells on the non-woven fabric occurs when the liquid temperature is higher than the predetermined temperature, and release of

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the captured cells from the non-woven fabric occurs when the liquid temperature is lower than the predetermined temperature. Claim 7 specifies that the polymer is poly(N-isopropylacrylamide). Claim 8 specifies that the physiologically active substance is, among others, an antibody. Claim 9 is drawn to a method for separating and recovering cells, which comprises: bringing a liquid containing cells into contact with a non-woven fabric which is bound with a polymer showing a hydrophobic nature at a temperature higher than a predetermined temperature and showing a hydrophilic nature at a temperature lower than the predetermined temperature and a physiologically active substance capable of binding to target cells, to thereby capture target cells on the non-woven fabric for separating the cells, releasing the captured cells from the non-woven fabric by changing the temperature of the non-woven fabric around the predetermined temperature, and recovering the cells released from the non-woven fabric. Claim 10 is drawn to a method for separating and recovering cells, which comprises: bringing a liquid containing cells into contact with the non-woven fabric in the treatment part using the separation and recovery apparatus according to claim 1 to capture target cells on the non-woven fabric for separating the cells from the liquid, releasing the captured cells from the non-woven fabric by changing the liquid temperature of the treatment part around the predetermined temperature, and recovering the cells released from the non-woven fabric.

Kim et al. teaches, e.g., at the abstract, a polypropylene membrane with poly-n-isopropylacrylamide (which has the property of liquefaction at a lower temperature rather than higher) grafted to it. At page 1169, at the first paragraph of "Experimental", the membrane is taught to be unwoven. Also on that page, in the paragraph bridging the columns, it is suggested that "a cell separation system with thermosensitivity (i.e., using grafted poly-n-

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isopropylacrylamide ) and an affinity of antibodies to the cell surface, which could be controlled by a change in temperature and could separate specific cells by affinity to an antibody” be constructed. Kim et al. exemplifies a system with every element of the claimed invention in combination except bound antibodies for cell separation. However, this was clearly suggested as set forth above. It would have been obvious to have used the poly-n-isopropylacrylamide grafted membrane of Kim et al. to create a cell separation apparatus having antibodies specific for the cells attached to the poly-n-isopropylacrylamide, and to have thus separated cells by binding them at the higher temperature and releasing them at the lower temperature, as suggested by Kim et al. The motivation to do so would have come from the suggestion, as well.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites “so as to capture the cells on the non-woven fabric captures when the liquid temperature is lower...” However, the word “captures” is confusing, as it does not fit into the grammar of the claim. It is not clear if words were omitted or if “captures” is a typographic error and should have been omitted.

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Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK  
6 July 2007

  
JAMES KETTER  
PRIMARY EXAMINER